To: National Organic Standards Board C/o Dan Giacomini, Chairperson, Materials Committee

From:

Kim Dietz, Co-Facilitator, Materials Working Group Gwendolyn Wyard, Co-Facilitator, Materials Working Group

Dear NOSB,

Please accept the following documents from the "Materials Working Group" (MWG) for discussion at the upcoming NOSB meeting in May 2008. Please feel free to publish these for public comment. Thank you in advance for the opportunity to collaborate in the materials discussions.

The Material Working Group was formed by an unaffiliated collection of individuals with technical and regulatory background. Participation in our group was open and available to any interested party. The MWG goal is to offer working papers to the NOSB on materials issues. We have been meeting weekly, via conference call, since February 2008.

Enclosed:

Materials Working Group Discussion Document (03/25/08) – What is an agricultural substance, and what makes a substance non-agricultural?

Appendix:

- A- Definitions of "agricultural"
- **B-** Summary of Options
- C- Impacts of deletion or changes to the definition of "nonagricultural" on NOP regulations.
- D- Decision Tree Option D
- E- Decision Tree Option F
- F- Questions for further consideration

Cc: Participants, Materials Working Group National Organic Program

Materials Working Group Discussion Document: What is an agricultural substance, and what makes a substance non-agricultural? March 25, 2008

Problem Statement:

The NOP permits the use of nonorganic ingredients for up to 5% of a product labeled as "organic." In order to be used as an ingredient in a product labeled as "organic," a nonorganic substance must be included on the National List, in either Section 205.605 (for nonagricultural substances) or Section 205.606 (for agricultural products).

A non-organically produced agricultural substance listed on 205.606 may be used only when the organically produced form of the substance is not commercially available. A non-agricultural substance that is listed on 205.605 is not subject to the requirement that the organically produced form be used if commercially available.

The current situation derives from the presumption that a substance categorized as nonagricultural cannot be organically produced since Section 205.102 requires that only an "agricultural product" can be labeled as "organic." However, the NOP definition of "nonagricultural" resulted in many ingredients derived from agricultural products being listed on 205.605. Examples include gums, citric acid or pectin. Yeast and bacterial cultures also are defined by the NOP as "nonagricultural."

Currently, processed food ingredients such as yeast, flavors, gums and glycerin listed in 205.605 are being produced in accordance with the Rule and labeled as "organic." However, because these substances are classified as "nonagricultural" on the National List, there is no requirement for handlers to use the organically produced form of these ingredients. This problem may create an obstacle to the expansion of organic production, and a disincentive for the improvement of the percentage organic in multi-ingredient organic products.

Another complicating factor in classifying some of the substances currently on 206.605 as agricultural is the NOP interpretation of 205.237(a) that all agricultural products fed to organically raised livestock (including as additives or supplements) must be certified organic. Currently, nonsynthetic, non-agricultural substances, such as mined minerals, yeast, and bacteria are permitted as feed additives and supplements. Therefore, if any ingredient now listed on 205.605 is determined to be agricultural, it can only be used as a feed supplement if it is organically produced. This is a concern for products like direct fed microorganisms (primarily yeast and bacteria), which are important livestock feed additives used for nutritional and digestive purposes. Currently, no market impact analysis has been conducted to determine how a change would affect the availability of these substances in livestock feed

Another problem has been noted in that the term "microorganism" as a category on §205.605 is being interpreted broadly. For instance, *Spirulina* (a filamentous cyanobacteria) and *Chlorella* (a single-celled algae) have been considered by some certifiers to be microorganisms, and permitted as non-organic food ingredients, while

both could potentially be cultivated organically. NOSB will need to clarify the definition of microorganism, given the development of novel products from non-traditional food organisms.

Background:

In July, 2005 the NOSB's Handling Committee submitted its "Recommendations Relative to "Agricultural" and "Nonagricultural" Substances." This included three recommendations:

1. A guidance document for defining agriculture as it applies to agricultural products. This guidance document defines "agricultural products" as "those that are managed by humans and derived from living organisms that are capable of photosynthesis including plants (Kingdom Plantae), cyanobacteria (Kingdom Monera) and the multi-cellular algae (Kingdom Protista) or derive their energy by absorption including animals (Kingdom Animalia) and the edible, fungi that produce multi-cellular fruiting bodies (ascocarp and basidiocarp) commonly referred to as mushrooms (Kingdom Fungi)."

This document also gives the meaning of "managed by humans" as "the intentional act of gathering, producing, raising, or growing, domestically or in designated wild-harvest areas, by persons for human or livestock consumption."

This document explicitly states that "yeasts have been considered nonagricultural and listed in section 205.605 along with other non-synthetics such as dairy cultures. Fungi that do not produce true fruiting bodies as the edible fungi (mushrooms) are not considered agricultural."

2. The re-definition of "nonagricultural substance" as follows:

Nonagricultural substance: A substance that is not a product of agriculture, such as a mineral or a bacterial culture

3. Assistance in defining a "nonagricultural substance" by use of the Decision Tree.

In September, 2006 the NOSB Joint Handling and Materials Committees issued another set of "Recommendations Relative to "Agricultural" and "nonagricultural" Substances for National List Consideration." This document recommended revising the definition of "nonagricultural substance" to read, "A substance that is not a product of agriculture, such as a mineral, that is used as an ingredient in an agricultural product." It also recommended, as a technical correction, moving "Dairy cultures" and "Yeast" from 205.605(a) to 205.606. This recommendation was again sent back for additional work, in light of the problems raised for livestock feed, among others.

Another discussion document on the definition of materials was issued by the Joint Handling and Materials Committees in October of 2007, and discussed at length at the November, 2007 NOSB meeting. This discussion document identified several "areas of confusion," including positing a "new paradigm" in which the concepts of "synthetic vs. nonsynthetic" and "agricultural vs. nonagricultural" form a single continuum. An

agricultural substance can become synthetic and it can also become nonagricultural, depending on how it is processed or manufactured. As noted in the conclusion, "Various NOSB committees have debated these issues since the formation of the NOSB."

Materials Working Group Discussion:

The Materials Working Group, a collection of individuals seeking to offer assistance to the NOSB in sorting out the areas of confusion, has been meeting weekly since early in 2008. One document developed (attached as Appendix A) is a compendium of definitions promulgated by the OFPA, the NOP rule, USDA and other Federal agencies, dictionaries, and other sources for terms such as "agricultural commodity," "agricultural product," and "consumption." We hoped to use this document in the future to develop a definition of "agricultural" that is specific enough to enable the definition of "nonagricultural" as anything not included in the definition of "agricultural".

While these definitions have led to helpful discussions none have provided a solution that satisfies the diverse interests of the group. There is general agreement that the definition of "nonagricultural" in the NOP is problematic, yet the various "agricultural product" and "agricultural commodity" definitions collected all leave out products and ingredients that are now being certified as organically produced, and are therefore presumably agricultural. For example, distilled spirits are generally excluded from status as an agricultural commodity, although alcohol is derived from agricultural products through naturally occurring biological processes, and is available as a certified organic agricultural product. Maple syrup is agricultural, but the tree, when turned into lumber, is classified by the Department as a non-agricultural product. In short, most of these definitions are aimed at sorting out agency jurisdictional boundaries rather than clarifying the meaning of these terms.

The group has also worked with modified decision trees, attempting to reach consensus on how various substances that have been petitioned for the National List would be classified. Examples showing the obstacles and outcomes of this exercise are attached as Appendices D and E.

There has also been some discussion about what might be changed in order to eliminate the need to distinguish between agricultural and nonagricultural products in the context of the National List, and what other problems would be created. Few disagree that some revision to the NOP regulations would be in order, but most consider any amendment to the OFPA to be a "deal breaker."

There is ongoing disagreement about whether all life—i.e., microbial products such as yeast and yogurt cultures--should be considered agricultural if it is managed for production, and therefore potentially organically produced. There has been considerable discussion that if micro-organisms were to be considered agricultural, microbial standards would have to be developed. The crops and livestock standards do not adequately address unique requirements of the culture and growth of micro-organisms. It has been pointed out that both yeast and alcohol are produced and processed using the same raw materials through similar methods, differing only in which part of the end

product—the organism or its waste product—is being marketed. In this respect, some have suggested that the processing standards adequately address the necessary processes and requirements for organic certification of yeast.

The example of the EU 2092/91 Annex VI provision for non-organic microorganisms, along with its definitions was also reviewed. It is noteworthy for identifying food additives, flavorings, and micro-organism preparations as nonagricultural. However, the EU has expressly recognized yeast in food and feed as eligible for organic production, and Article 20 of the new EU Council Regulation No. 834/2007 provides general rules for the production of organic yeast. The first general rule, is that only organically produced substrate shall be used and "other" products and substances used in its production must be authorized under Article 21. The second rule is that in organic food or feed, organic yeast may not be present together with non-organic yeast. The third and final rule is that in the future there may be detailed production rules adopted in accordance with the procedure under the EU regulation.

Some have pointed out that these rules are analogous to the existing processing standards in the NOP regulation. While they may not embrace every specific technical situation in the production of yeast, they do provide sufficient guidelines to certifiers in order to conduct certification of yeast producing operations based on the specifics of the Organic Systems Plan. More importantly, they accommodate the actual conditions in which yeast is produced rather than trying to fit yeast production into the crop or livestock standards. In this respect the labeling of yeast as "organic" reflects a processed product produced in accordance with the composition and handling requirements of an organic product. The "agricultural" status of such a product is its relation to and reliance on raw agricultural material for the production of a product used as food or feed.

Others have suggested using annotations to require that nonagricultural yeast be produced using organically produced media. The annotation for yeast currently prohibits the use of petrochemical substrate and sulfite waste liquor. There is disagreement about how consistently the current annotation is being enforced and how enforceable an annotation that requires verification of an organic ingredient by a conventional processor might be. More clarification is needed about the role of annotations, especially for non-organic agricultural substances.

Options to Consider:

The following are ideas that have been discussed by this group as some possible scenarios for resolving the problems identified. Additional analysis is needed of the potential impact of each of these on the industry and on consumer perception of the standard. These alternatives are included here as avenues to be explored, not recommended actions. These options are not comprehensive, and imply no order of preference. For a comparison of various alternatives discussed, refer to Appendix B.

Option A. Status Quo

The current regulation remains unchanged, except for the amendment of the National List through the petition process.

Discussion:

Not changing the regulation will take the least amount of effort from the NOSB and NOP. The NOSB will make its findings on what is agricultural and what is non-agricultural on a case-by-case basis in the context of the current definitions. Certifiers, producers, and handlers will continue to operate as they have in making decisions as to what is agricultural and what is non-agricultural, and continue to live with the apparent contradiction contained in the definition of 'non-agricultural.'

The Problem Statement summarizes the ongoing dilemmas created by this option.

Option B. Drop 'nonagricultural" from the regulation and apply commercial availability to 605 & 606

• Revise the regulations so that the title of Section 205.605 becomes **Nonorganic** substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))." Revise the regulatory text as follows:

The following nonagricultural organic substances may be used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))" only in accordance with any restrictions specified in this section. If used in processed products labeled as "organic", such substances may only be used when they are not commercially available in organic form.

Delete the definition of "Nonagricultural substance" in Section 205.2, and identify other places in the rule where the term "nonagricultural substance" is used that may need to be revised accordingly.

Refer to Appendix C for suggested revisions needed in the regulation to accommodate the deletion of 'nonagricultural'.

Discussion:

This approach would solve the problem of uncertainty about the agricultural status of many items on 205.605, some of which are derived from agricultural products or produced using at least 95% agricultural ingredients at formulation, by removing their classification as "nonagricultural." The distinction between "agricultural" and "nonagricultural" ingredients is not made in OFPA, which refers only to use of ingredients that are "not organically produced" (6510(a)(4)). By leaving this section ambiguous and inserting the requirement for organically produced forms when they are commercially available, yeast and other products could be produced organically without being categorized as "agricultural" for the purposes of livestock feed. Section 205.606 would continue to list only those products that are unambiguously agricultural.

Potential problems with this approach relate to the requirement in Section 205.102 that permits use of the term "organic" to refer to "any agricultural product..." However, this

is not currently being interpreted and applied consistently by the NOP. For example, flavors are listed on § 205.605 but permitted to be certified organic; spirulina and chlorella are allowed as nonagricultural microorganisms yet spirulina is available as a NOP certified organic product. Therefore, without a clear definition that encompasses any living organism that is cultivated for human or livestock consumption, products such as yeast and microbial cultures could be challenged as ineligible for organic status. A possible remedy for this problem could be to delete the word "agricultural" as a modifier of "product" throughout the NOP regulations, but this may have additional ramifications that have not been considered.

Option C. Change the definition of non-agricultural to drop mention of bacterial cultures and other substances

• Revise the definition of "Nonagricultural substance in Section 205.2 to read, "A substance that is not a product of agriculture, such as a mineral."

Discussion:

This would entail removing yeast and microorganisms from Section 205.605 and petitioning them to Section 205.606. It might also entail revision of the livestock feed requirements to be consistent with those for human consumption, by permitting the use of up to 5% nonorganic agricultural products as livestock feed, subject to the commercial availability restriction. This could be politically unacceptable, as some would characterize it as "weakening" the standards. However, it would be one way of revising the regulations without changing the structure of the National List.

Other objections to characterizing yeast and other microbial products as "agricultural" that have been expressed include the lack of specific standards for organic production of microorganisms and the concern that a definition of "agricultural" should be limited to products originating on a farm, and that are either cultivated in the soil or raised in soil-based systems. Such concerns are related to opposition to organic certification of hydroponics and other non-soil based production operations, which the NOP currently permits.

Option D: Change the definition of Non-Agricultural (retain mention of bacterial culture)

a) Revise the definition of "Nonagricultural substance in Section 205.2 to read, "A substance that is not a product of agriculture, such as a mineral or bacterial culture," and adopt as guidance the NOSB 2005 clarification of definition of agricultural product as:

"those that are managed by humans and derived from living organisms that are capable of photosynthesis including plants (Kingdom Plantae), cyanobacteria (Kingdom Monera) and the multi-cellular algae (Kingdom Protitsa) or derive their energy by absorption including animals (Kingdom Animalia) and the edible, fungi that produce multi-cellular fruiting bodies (ascocarp and basidiocarp) commonly referred to as mushrooms (Kingdom Fungi)."

b) Revise the regulations so that the title of Section 205.605 becomes Nonorganic substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))." Revise the regulatory text as follows:

"The following nonagricultural organic substances may be used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))" only in accordance with any restrictions specified in this section."

c) Clarify further that nonorganic substances in § 205.605 may be used in formulation of multi-ingredient processed organic products. For example organic bakers yeast can be produced organically, using a non-organic starter yeast, that is cultured in accordance with the 95/5 composition requirements and handling requirements of § 205.271. Organic koji culture can also be produced using pure laboratory strains that are non-organic, and cultured in accordance with the organic composition and handling requirements.

Discussion:

This option permits use of all substances identified as nonorganic on § 205.605, but does not require organic sources when available. Substances that cannot be determined to be strictly agricultural would be included here, without being identified as "nonagricultural." This means there is no barrier to prevent development of organic forms, as new technology or better supplies of organic materials may be developed. It would also be less burdensome than requiring use of organic forms of substances on this list, if they are commercially available, since most of these items could never be produced organically. This approach would avoid the need to revise the livestock feed standards, since additives and supplements listed as "nonsynthetic" on § 205.605 do not have to be organic to be fed to livestock. It would also avoid major restructuring of the National List, and would be compatible with the EU regulations for organic yeast.

This option would not offer the incentive of a requirement to use commercially available organic forms of ingredients whose agricultural status is ambiguous. The only way to address this problem would be to petition these substances for 205.606 with a clear rationale for considering them to be agricultural products.

Option E. Add definitions for "Agricultural System"

- Revise the definition of "Nonagricultural substance in Section 205.2 to read, "A substance that is not a product of agriculture."
- Add a definition for "Agricultural System" in Section 205.2 to read. "For this part, an agricultural system is that is a land based system that cultivates soil producing crops, livestock or poultry.

- Add a definition for "Non Agricultural System" in Section 205.2 to read. "Any system that is not a system that is land based and cultivates soil producing crops, livestock or poultry.
- Revise 205.605 to read, "§ 205.605 Nonorganically produced substances from Non Agricultural Systems allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
- Revise 205.606 to read. "§ 205.606 Nonorganically produced substances from Agricultural Systems allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Discussion:

In considering public policy and the intention of Congress, it becomes necessary to further define those systems of agriculture that express the principles of organic farming. For this reason, a definition for "Agricultural Systems" should be added.

This change would effectively remove the issue of what is agricultural and focus on which products could be produced by an organic system. The definition of an agricultural system would then determine the environments where organic integrity can be established. Further, this definition prevents the unrelenting expansion of organic into systems in which the regulation has not provided standards.

By doing this and altering the titles of the National List, we are able to distinguish between substances that will never be produced by organic systems and those that may. By applying commercial availability requirements on ingredients in § 205.606, there is an incentive for innovation and continuous expansion of available organic substances.

This option as presented would however only remove the issue of "what is agricultural" if everyone agreed that an agricultural system is a land based system that cultivates soil producing crops, livestock or poultry. Considerable discussion revolved around the question of whether soilless operations such as hydroponics, aquaculture or yeast produced in a facility are provided for under the NOP definition of 'organic production' and thus eligible for organic certification. The NOP defines organic production as follows:

A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Some argue that while the production of certain products may not utilize soil or take place on a farm, their production or handling is related to, used in, or concerned with agriculture and therefore part of an "agricultural system". Furthermore the inputs used and practices involved directly and indirectly address the components of the organic production definition because of upstream and downstream environmental implications

and pest management requirements placed on handling facilities. Others argue that plants or microbes grown in a facility are not managed subject to diverse organic management practices, but instead represent an input-substitution model, in that they are identical to conventional production with organic materials replacing synthetic conventional inputs. The crops and livestock standards go beyond inputs and source of seed/stock, whereas it is hard to envision a more complex set of standards for microbial products.

Option F – Merge 205.605 and 205.606

- Merge 205.605 and 205.606, and delete mention of agricultural/nonagricultural in the title:
- No need to distinguish between synthetic and nonsynthetic items on this section of the list:
- Drop the requirement for commercial availability on the combined list, including that in § 205.301(b);
- Develop a better system for petitioning to remove items as they become commercially available; and
- Drop the definition of non-agricultural.

Discussion

Congress required that only ingredients on the National List be allowed in organic processed products. By removing the definition of 'non-agricultural' and consolidating the lists, processors can then use any item on the list in an organic product. If an organic source becomes available, then one can petition to remove the substance from the list. If processors do not want to use the now available product, or formulate with a minor ingredient not available in organic form, they still have the option to use non-organic forms and make a 'made with' claim. Microbial products that become available in organic form would be required for processed food products but not as feed additives. This approach would save NOSB considerable time trying to determine what is agricultural, nonagricultural, synthetic or nonsynthetic.

This position may be countered by pointing out that products currently may be placed on 606 if they are potentially commercially unavailable—this is a dynamic, dialectical situation that can change dramatically in a short time due to market manipulations, crop failures, and so on. That the determination of "commercial unavailability" is made by the certifier, not by the NOSB, is a necessary reflection of that fluid situation. Even with an expedited process, the burden of petitioning a substance for 606, either on or off, is major and not likely to be feasible for small producers who may begin producing an organic minor ingredient. It is also difficult for a larger operation to commit to producing a new organic ingredient in sufficient quantities to be commercially available if it is on 205.606 and there is no requirement that the organic form be used. This approach may not solve the problem of the ever-increasing list of non-organic ingredients that are being petitioned, and would add to the existing problems of verifying commercial availability.

Summary:

The members of the Materials Working Group represent a broad spectrum of backgrounds and segments of the industry. All have strong opinions about a subject with extensive implications for the meaning of the organic label and its potential for application to all aspects of food and agriculture, including a host of other consumer goods that were not considered when the OFPA was drafted. We recognize that it will not be easy to resolve the issues surrounding the definition of "nonagricultural substance" and its impact on what products may—or may not--eventually be able to be organically produced.

Some of the objectives and underlying assumptions that have been articulated by this group include:

- Our primary objective is to help clarify definitions so that materials will be consistently placed on appropriate sections of the National List, and so that organic producers and handlers will be able to comply with the regulations.
- National List requirements should be crafted so as to encourage the development of organic sources of food, ingredients and feed.
- Changes to the regulations should be minimized, in order to avoid disrupting organic production and handling systems or creating confusion for the public.
- Resolution must be consistent with the OFPA.
- "Agricultural," like "synthetic," is not a trait inherent to any substance that can be positively identified; it is a qualitative statement about how the substance was produced.

We hope that this discussion has helped resolve some questions and clarify others. Attached as Appendix F are some questions we have tried to address as a group, some of which have proved controversial, as well as questions that require additional clarification by the NOSB and the NOP, and input from the public.

We appreciate the effort devoted by the NOSB to moving toward a resolution of these complex issues, and offer this discussion document as background to further work on the subject. We will continue to offer whatever support we can to further this effort.

LIST OF MWG PARTICIPANTS (affiliations are for identification purposes only and do not indicate support for any or all of the opinions expressed):

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List of Attachments:

- A: Definitions of "agricultural"
- B. Summary of Options
- C. Impacts of deletion or changes to definition of "nonagricultural" to NOP regulation
- D. Decision tree, option D
- E. Decision tree, option F
- F. Questions for further discussion

Appendix A: Definitions of "Agricultural"

Materials Working Group

The Rule [7 CFR 205.2 Terms defined] uses the statutory OFPA definition [6502(1)]

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Term in the OFPA	Definitions (Source)				
"agricultural commodity"	Sec. 1a. Definitions (4) Commodity The term ``commodity" means wheat, cotton, rice, corn, oats, barley, rye, flaxseed, grain sorghums, n feeds, butter, eggs, Solanum tuberosum (Irish potatoes), wool, wool tops, fats and oils (including lard, tallow, cottonseed oil, peanut oil, soybean oil, and all other fats and oils), cottonseed meal, cottonseed peanuts, soybeans, soybean meal, livestock, livestock products, and frozen concentrated orange juice and all other goods and articles, except onions as provided in section 13-1 of this title, and all services rights, and interests in which contracts for future delivery are presently or in the future dealt in. 7 USC1a TITLE 7—AGRICULTURE CHAPTER 1COMMODITY EXCHANGES				
"agricultural commodity"	Agricultural Commodity: Agricultural commodity is defined in the Farm Bill as any agricultural commodity or products thereof produced in the United States. Agricultural Commodity: Grain and non-grain crops, vegetables, fruits, nuts, nursery plants, floriculture, Christmas trees, maple tree sap, animals, products from animals such as milk, eggs, etc., and any other agricultural production, excluding timber, forest, and forest products. http://www.cropusainsurance.com/CropUSA/Glossary.asp				
"agricultural commodity"	7 USC 7901. DEFINITIONS [2002 Farm Bill] (4) Covered commodityThe term ``covered commodity" means wheat, corn, grain sorghum, barley, oats, upland cotton, rice, soybeans, and other oilseeds. (8) Loan commodityThe term `loan commodity' means wheat, corn, grain sorghum, barley, oats, upland cotton, extra long staple cotton, rice, soybeans, other oilseeds, wool, mohair, honey, dry peas,				

	lentils, and small chickpeas.
	(9) Other oilseedThe term ``other oilseed" means a crop of sunflower seed, rapeseed, canola, safflower, flaxseed, mustard seed, or, if designated by the Secretary, another oilseed.
"agricultural	7 USC 7916. PLANTING FLEXIBILITY. [2002 Farm Bill]
commodity"	(b) Limitations Regarding Certain Commodities
	(1) General limitationThe planting of an agricultural commodity specified in paragraph (3) shall be prohibited on base acres unless the commodity, if planted, is destroyed before harvest.
	(2) Treatment of trees and other perennialsThe planting of an agricultural commodity specified in paragraph (3) that is produced on a tree or other perennial plant shall be prohibited on base acres.
	(3) Covered agricultural commoditiesParagraphs (1) and (2) apply to the following agricultural commodities:
	(A) Fruits.
	(B) Vegetables (other than lentils, mung beans, and dry peas).
	(C) Wild rice.
"agricultural" per FAS, USDA	Agricultural products, sometimes also referred to as "food and fiber" products, cover a broad range of goods from unprocessed bulk commodities like soybeans, feed corn, wheat, rice, and raw cotton to highly-processed, high-value foods and beverages like sausages, bakery goods, ice cream, beer and wine, and condiments sold in retail stores and restaurants.
	All of the products found in Chapters 1-24 of the U.S. Harmonized Tariff Schedule (except for fishery products in Chapters 3 and 16, manufactured tobacco products like cigarettes and cigars in Chapter 24, and spirits in Chapter 22) are considered agricultural products. Agricultural products within these chapters generally fall into the following categories: grains, animal feeds, and grain products (like bread and pasta); oilseeds and oilseed products (like soybean oil and olive oil); livestock, poultry and dairy products including live animals, meats, eggs, and feathers; horticultural products including all fresh and processed fruits, vegetables, tree nuts, as well as nursery products, and beer and wine; unmanufactured tobacco; and tropical products like sugar, cocoa and coffee.
	Certain other products outside of Chapters 1-24 are also considered agricultural products. The most significant are essential oils (Chapter 33), raw rubber (Chapter 40), raw animal hides and skins (Chapter 41), and wool and cotton (Chapters 51-52).

Not considered "agricultural" per FAS USDA	The major products derived from plants or animals which are not considered "agricultural" because of their manufactured nature are cotton thread and yarn; fabric, textiles and clothing; leather and leather articles of apparel; cigarettes and cigars; and spirits. Note USDA's trade databases also include selected "non-agricultural" harmonized tariff schedule commodities. The non-agricultural commodities which have been included typically fall into two groups: manufactured products derived from plants or animals like yarns, fabrics, textiles, leather, articles of apparel, cigarettes and cigars, spirits; or products used in the farm production process like agricultural chemicals, fertilizers, and farm machinery. Fishery products are included as non-agricultural products because of their food value and the fact that FAS collaborates with the seafood industry to promote exports. Solid wood products are also included as a non-agricultural product because FAS collaborates with U.S. industry to promote exports of these products as well.				
"(agricultural) product"	Definition of the adjective "agricultural": of, relating to, used in, or concerned with agriculture ["agricultural" is the adjectival form of "agriculture"]. THUS, "agricultural product" means "product of agriculture."				
"(agricultural) product" = "product of agriculture"	Definitions of the noun "agriculture":				
	The science, art, and business of cultivating soil, producing crops, and raising livestock; farming. [American Heritage Dictionary]				
	farming; the science and art of cultivating fields and producing crops, livestock, or poultry. [Scribner-Bantam English Dictionary]				
	1. the science, art, or occupation concerned with cultivating land, raising crops, and feeding, breeding, and raising livestock; farming.				
	2. the production of crops, livestock, or poultry.				
	3. Agronomy [the science of soil management and the production of field crops] [http://dictionary.reference.com/browse/agriculture]				
	The art or science of cultivating the ground, including the harvesting of crops, and the rearing and management of live stock; tillage; husbandry; farming. [Webster's Dictionary, 1913]				
	"Agriculture" derives from the Latin "agricultura": "ager" (field) + "cultura" (cultivation)				

"farming" Operation of a farm; agriculture. [Scribner-Bantam English Dictionary] "farm" (noun) 1 Single portion of land under cultivation, with its buildings; 2 Land where certain animals are fox farm. [Scribner-Bantam English Dictionary] "field" per the Rule An area of land identified as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [
"field" per the Rule "Land requirements" per the Rule "Certified Organic Farm" per OFPA "raw" fox farm. [Scribner-Bantam English Dictionary] An area of land identified as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a production operation [§205.2 Terms defined as a discrete unit within a product of [§205.2 Terms defined as a discrete unit within a product of [§205.2 Terms defined as a discrete unit within a product of [§205.2 Terms defined as a discrete unit within a product of [§205.2 Terms defined as a discrete unit within a product of [§205.2 Terms defined as a discrete unit within	
"Land requirements" per the Rule "Certified Organic Farm" per OFPA The term "certified organic farm" means a farm, or a portion of a farm, or site where agriculated by the certifying agent under this chapter utilizing a system of organic farming as described by this chapter. [7 USC 6502(4)] "raw" 1 uncooked; 2 with the skin rubbed off (raw wound per RT); 3 natural; unprocessed; not man	ed]
requirements" per the Rule "Certified Organic Farm" per OFPA The term "certified organic farm" means a farm, or a portion of a farm, or site where agriculture a	
Organic Farm" per OFPA products or livestock are produced, that is certified by the certifying agent under this chapter of utilizing a system of organic farming as described by this chapter. [7 USC 6502(4)] "raw" 1 uncooked; 2 with the skin rubbed off (raw wound per RT); 3 natural; unprocessed; not man	[§205.202]
, , , , , , , , , , , , , , , , , , , ,	
raw silk. [Scribner-Bantam English Dictionary]	ufactured, as
"processed" Past tense or past participle of the transitive verb "process":	
Process: to cause to undergo some operation; to prepare by a particular process. [Scribner-English Dictionary]	3antam
Process: a: to subject to a special process or treatment (as in the course of manufacture or f development) b: to subject to or handle through an established usually routine set of procedu [Merriam-Webster online Dictionary relevant definitions]	
"processing" Gerund of the transitive verb "process"	

"processing" per OFPA	(17) Processing . Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, <u>fermenting</u> , distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container. [7 USC 6502(17); also 7 CFR 205.2]					
"livestock" per OFPA	(11) Livestock . The term "livestock" means any cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other non-plant life. [7 USC 6502(11)]					
"livestock" per the Rule [7 CFR 205.2]	Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.					
	NOTE: NOP definition of "livestock" (" shall not include aquatic animals for the production of food") directly contradicts the OFPA definition ("means fish used for food").					
"food"	Any substance taken into and assimilated by a plant or animal to keep it alive and enable it to grow; nourishment; nutriment. Webster's New World Dictionary					
"consumption"	 1 a: a progressive wasting away of the body especially from pulmonary tuberculosis. b: tuberculosis 2 a: the act or process of consuming <consumption food="" of=""> <consumption of="" resources=""> b: use by or exposure to a particular group or audience <the consumption="" document="" for="" intended="" not="" public="" was=""></the></consumption></consumption> 3: the utilization of economic goods in the satisfaction of wants or in the process of production resulting chiefly in their destruction, deterioration, or transformation. Merriam-Webster Online Dictionary 					
	 a. The act or process of consuming. b. The state of being consumed. c. An amount consumed. d. A progressive wasting of body tissue. e. Pulmonary tuberculosis. No longer in scientific use. Economics The using up of goods and services by consumer purchasing or in the production of other 					

goods.

- 3. Pathology
 - a. A progressive wasting of body tissue.

Pulmonary tuberculosis. No longer in scientific use.

American Heritage Dictionary

- 1. the process of taking food into the body through the mouth (as by eating)
- 2. involving the lungs with progressive wasting of the body [syn: pulmonary tuberculosis]
- 3. (economics) the utilization of economic goods to satisfy needs or in manufacturing; "the consumption of energy has increased steadily"
- the act of consuming something WordNet

NOTE: The facts that (1) the OFPA definition of livestock includes the restrictive phrase "fish **for food**" and (2) the OFPA definition of "agricultural product" includes the defined term "livestock" strongly supports the position that the term "consumption" in the definition of "agricultural product" should be interpreted broadly, i.e., to mean more than "the process of taking food into the body" (". . . for food"). This interpretation is consistent with the NOP's statement "Certification of agricultural products that meet NOP standards" dated August 23, 2005; "consumption" means ". . . irrespective of the end use of the product" (to use the language used by NOP on August 23, 2005).

"organic" per the Rule	Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part. [§205.2]
"organic matter" per the Rule	Organic matter. The remains, residues, or waste products of any organism. [§205.2]

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Synthesis:

An "agricultural product" comprises:

- (a) Any agricultural commodity established by the Congress or the Secretary of Agriculture;
- (b) Any "crop" (other than livestock) produced on a "farm" [e.g., mushrooms are a recognized vegetable and are grown on a farm]; and
- (c) Any livestock, whether raised on a farm or not ("wild game" is specifically cited);
- (d) Any fish used for food (by humans, plants, or animals); or
- (e) Any product derived from any of the above;
- (f) If marketed for any use by humans or livestock.

What is not an "agricultural product" (but some of these may still be able to bear an "organic" label claim) may be:

- (a) Mined minerals and products thereof [let's not get into the oyster shell calcium carbonate issue here];
- (b) Timber, forest, and forest products [consistently excluded from listings of "agricultural commodities"];
- (c) Any wild crop [not grown on a "farm"];
- (d) Fish produced for a purpose other than food for humans, other animals, or plants;
- (e) Microorganisms that are cultured on synthetic/non-agricultural substances.

Appendix B: Summary of Options Materials Working Group

Option	Title of 605	Commercial availability	Definition of nonagricultural	Microorganisms	Effect on Livestock Feed
A. Status Quo	Contains substances that are permitted as non-organic, non-agricultural ingredients permitted to be used in processed products labeled as 'organic.'	Commercial availability applies to 606 but not 605.	A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.	Allowed on 605, not on 606.	Agricultural ingredients must be organic. Microbials are considered a non-synthetic, non-agricultural ingredients permitted as feed additives and feed supplements.
B. Drop "nonagricultural" from the regulation and apply commercial availability to 605 & 606	Nonorganic substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s)).	Commercial availability applies to all listings in 605 & 606	Deleted (see appendix C)	Could be on 605 or 606	Not clear
C. Change non- agricultural definition, (drop bacterial culture)	No change	No change	A substance that is not a product of agriculture, such as a mineral.	Goes to 606	Requires organic yeast for feed
D: Change definition of Non- Agricultural (retain bacterial culture)	Nonorganic substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s)).	Commercial availability does not apply to 605, it does to 606	A substance that is not a product of agriculture, such as a mineral or bacterial culture. (See appendix C)	Could be on both 605 and 606	Non-organic sources not required for feed
E. Add definitions "Agricultural	"§ 205.605 Nonorganically produced substances from Non Agricultural	No change	"A substance that is not a product of agriculture."	Would be on 205.605	Micro-organisms would be considered from non-agricultural systems - ok for

Option	Title of 605	Commercial availability	Definition of nonagricultural	Microorganisms	Effect on Livestock Feed
System	Systems allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." 205.606 – "Nonorganically produced substances from Agricultural Systems allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."		ADD: agricultural system: For this part, an agricultural system is that is a land based system that cultivates soil producing crops, livestock or poultry. (also add non-agricultural system)		feed
F. Merge 605 & 606	Merge 605 and 606, delete mention of	No requirement for commercial	Delete	Would be allowed as nonorganic, could	If nonsynthetic microorganisms remain on
No commercial availability	agricultural/ nonagricultural in title	availability requirement on combined list, delete also from 205.301		petition to remove	combined list as nonsynthetic, would be allowed for feed. If dropped from list as organically available, impact of feed is not clear.

Appendix C - Impacts Materials Working Group

Impacts of deletion or changes to the definition of "nonagricultural" on NOP Regulations

Option B: Drop "nonagricultural" from the regulation and apply commercial availability to 605 & 606

Revise the regulations so that the title of Section 205.605 becomes **Nonorganic substances** allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

Delete the definition of "Nonagricultural substance" in Section 205.2, and identify other places in the rule where the term "nonagricultural substance" is used that may need to be revised accordingly.

There are 8 places in the regulation where the word "non-agricultural" appears. Under Option B the following suggested revisions to the regulation would be needed: (deletions noted in strike-through format, additions are <u>underlined</u>)

#1

Section Contents

Subpart G – Administration National List of Allowed and Prohibited Substances

§ 205.605 Nonagricultural (nonorganic) Nonorganic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

#2 & #3

Subpart 8 - Definitions

205.1 Terms Defined

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

#4

Subpart B - Applicability

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

- (c) Non<u>organic agricultural</u> substances used in or on processed products, except as otherwise provided in §205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606;

#5

Subpart C - Organic Production and Handling Requirements

- § 205.270 Organic handling requirements.
- (a) Mechanical or biological methods including but not limited to.....or otherwise manufacturing...the agricultural product for market.
- (b) **Nonorganic agricultural** substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:
- (1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to § 205.301(b), if not commercially available in organic form.
- (2) In or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(c).

<u>#6</u>

Subpart D - Labels, Labeling, & Marketing

- § 205.301 Product composition.
- (b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced or unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part and commercially unavailable in organic form. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

<u>#7 & #8</u>

Subpart G Administrative

§ 205.605 **nonagricultural** (nonorganic) **Nonorganic** substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

The following **non<u>organic agricultural</u>**-substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section. <u>If used in processed products labeled as "organic"</u>, such substances may only be used when they are not commercially available in organic form.

Impact to Option D: Change definition of Non-Agricultural (retain bacterial culture)

Revise the regulations so that the title of Section 205.605 becomes **Nonorganic** substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

There are 8 places in the regulation where the word "non-agricultural" appears. Under Option D, 7 suggested revisions to the regulation would be needed:

<u>#1</u>

Section Contents

Subpart G – Administration National List of Allowed and Prohibited Substances

§ 205.605 **Nonagricultural** (nonorganic) **Nonorganic** substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

#2

Subpart 8 - Definitions

205.1 Terms Defined

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or bacterial culture. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

#3

Subpart B - Applicability

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

- (c) Non<u>organic agricultural</u> substances used in or on processed products, except as otherwise provided in §205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606;

#4

Subpart C - Organic Production and Handling Requirements

- § 205.270 Organic handling requirements.
- (a) Mechanical or biological methods including but not limited to.....or otherwise manufacturing...the agricultural product for market.
- (b) **Non**organic **agricultural** substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:
- (1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to § 205.301(b), if not commercially available in organic form.
- (2) In or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(c).

#5

Subpart D - Labels, Labeling, & Marketing

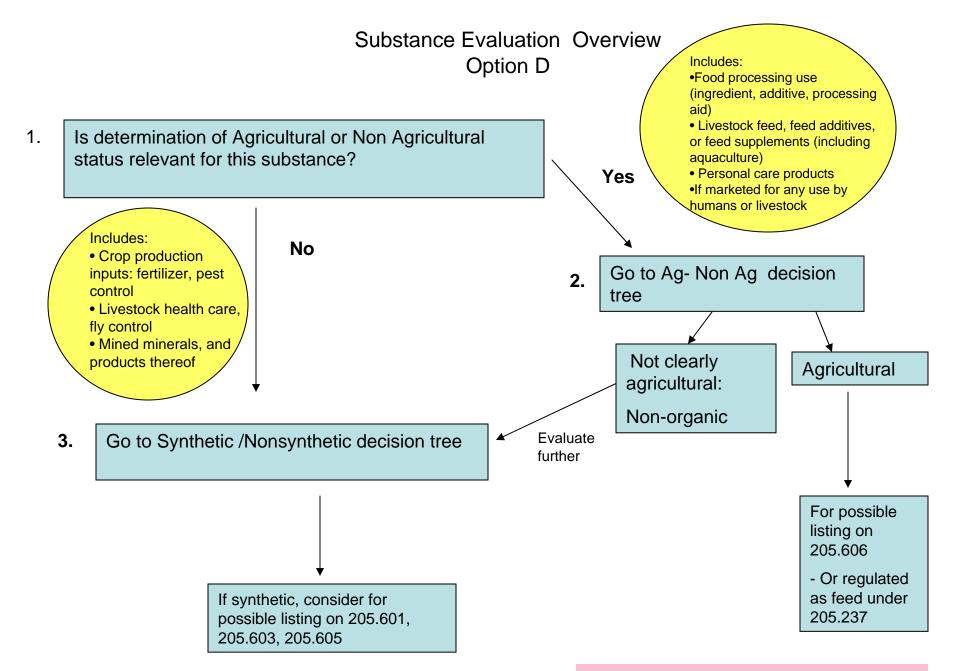
- § 205.301 Product composition.
- (b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless consistent with § 205.605 of the National List or consistent with 205.606 of the National List and not commercially available in organic form. or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §205.303.

<u>#6 & #7</u>

Subpart G Administrative

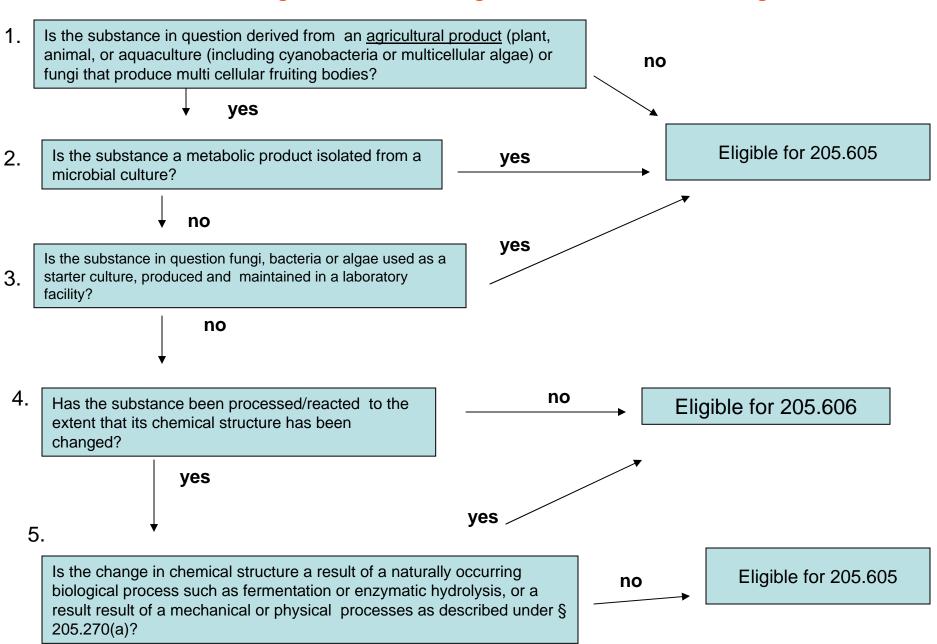
§ 205.605 **nonagricultural** (nonorganic) **Nonorganic** substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

The following **non<u>organic agricultural</u>** substances may be used as <u>ingredients</u> in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

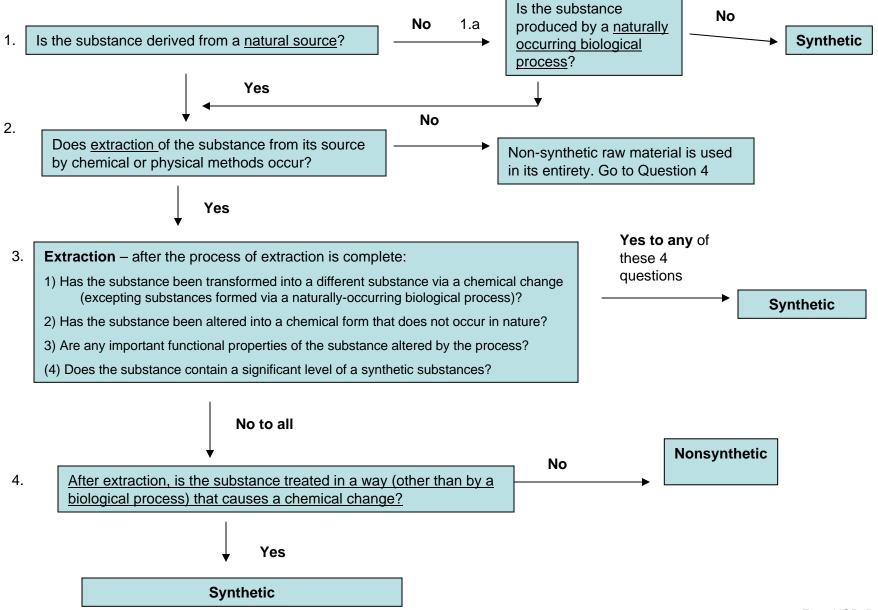


Criteria for Determining Agricultural vs. Non-Organic Substances for

Generic Ingredients Used in Organic Production and Handling



Proposed Decision Tree to Distinguish Synthetic and Nonsynthetic Substances



Relevant Definitions

Underlined items are defined here:

Substance: An element, molecular species, or chemical mixture that possesses a distinct identity (e.g., having a separate Chemical Abstracts Service (CAS) number, Codex International Numbering System (INS) number, or FDA orother agency standard of identity).

Natural source: Naturally occurring mineral, plant, or animal matter used to obtain non-synthetic inputs for organic production or handling.

Naturally occurring biological process: Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.

Extraction: The removal of a substance from a natural source by any chemical (e.g., solvent extraction, chemical precipitation) or physical (e.g., mechanical pressure, centrifugation, heating) manner and with any substance.

Formulation (manufacturing) - The manufacture of an agricultural or handling substance that is derived from a synthetic substance, a substance extracted from a natural source or produced by a naturally occurring biological process. Formulation is a synonym for manufacturing as the term is used in the OFPA definition of "synthetic".

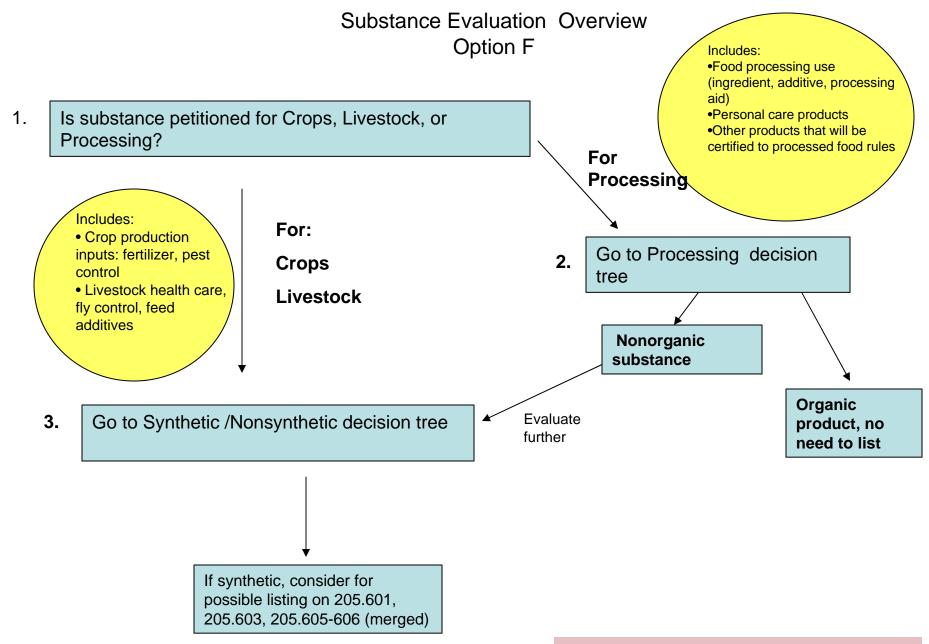
Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Clarification: those products that are managed by humans and derived from living organisms that are capable of photosynthesis including plants (Kingdom Plantae), cyanobacteria (Kingdom Monera) and the multi-cellular algae (Kingdom Protista) or derive their energy by absorption including animals (Kingdom Animalia) and the edible, fungi that produce multi-cellular fruiting bodies (ascocarp and basidiocarp) commonly referred to as mushrooms (Kingdom Fungi).

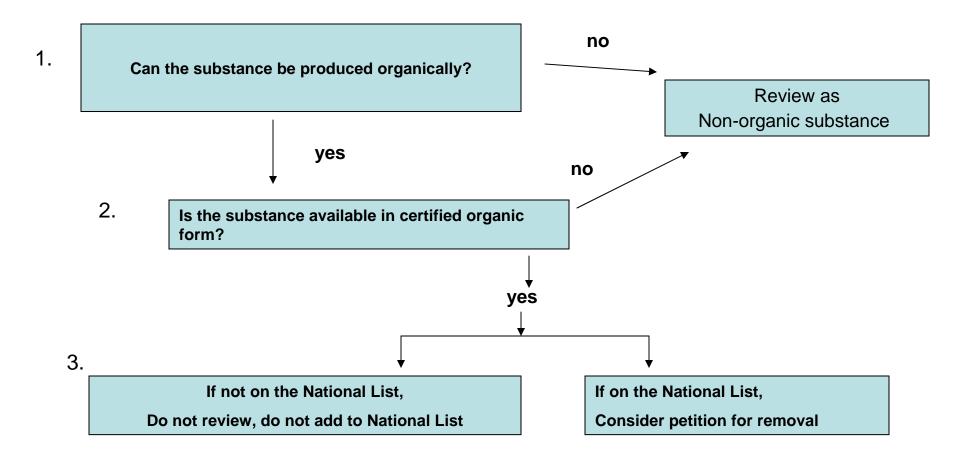
Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or bacterial culture

Chemical change – an occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of "substance").

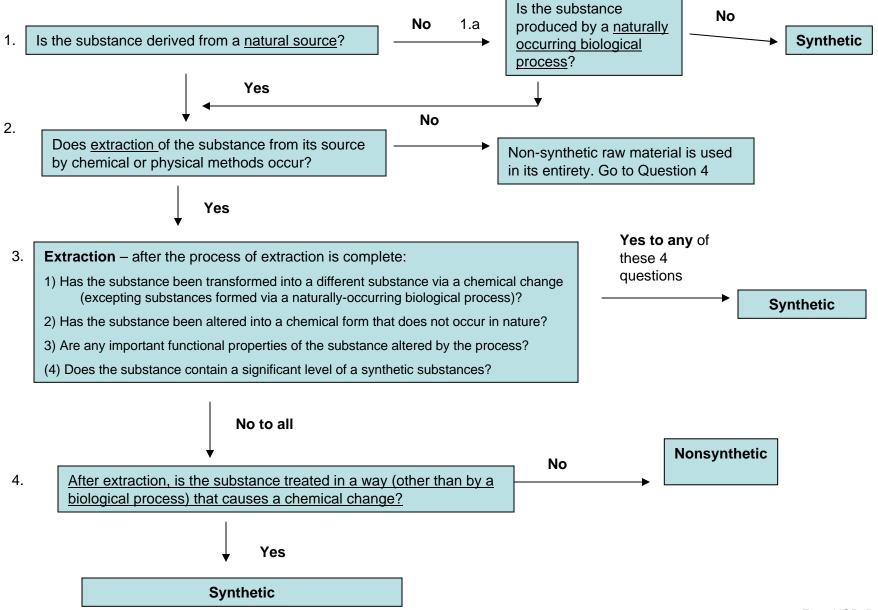
Source: NOP Recommended Framework to Further Clarify the Definition of Synthetic, March 9, 2006, with additions in blue.



Criteria for Reviewing Ingredients & Processing Aids Used in Organic Handling



Proposed Decision Tree to Distinguish Synthetic and Nonsynthetic Substances



Relevant Definitions

Underlined items are defined here:

Substance: An element, molecular species, or chemical mixture that possesses a distinct identity (e.g., having a separate Chemical Abstracts Service (CAS) number, Codex International Numbering System (INS) number, or FDA orother agency standard of identity).

Natural source: Naturally occurring mineral, plant, or animal matter used to obtain non-synthetic inputs for organic production or handling.

Naturally occurring biological process: Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.

Extraction: The removal of a substance from a natural source by any chemical (e.g., solvent extraction, chemical precipitation) or physical (e.g., mechanical pressure, centrifugation, heating) manner and with any substance.

Formulation (manufacturing) - The manufacture of an agricultural or handling substance that is derived from a synthetic substance, a substance extracted from a natural source or produced by a naturally occurring biological process. Formulation is a synonym for manufacturing as the term is used in the OFPA definition of "synthetic".

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Clarification: those products that are managed by humans and derived from living organisms that are capable of photosynthesis including plants (Kingdom Plantae), cyanobacteria (Kingdom Monera) and the multi-cellular algae (Kingdom Protista) or derive their energy by absorption including animals (Kingdom Animalia) and the edible, fungi that produce multi-cellular fruiting bodies (ascocarp and basidiocarp) commonly referred to as mushrooms (Kingdom Fungi).

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or bacterial culture

Chemical change – an occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of "substance").

Source: NOP Recommended Framework to Further Clarify the Definition of Synthetic, March 9, 2006, with additions in blue.

APPENDIX F: Questions for further consideration

1. Can the problems identified be solved without changing the regulation? If not, what is the least disruptive change that can be made?

Our discussions did not reveal a clear path to resolution that did not entail at least revising the definition of "nonagricultural." The options identified are all potential ways that this can be accomplished, with varying levels of regulatory revision. More clarification is needed about the proper use of annotations on the National List, especially with regard to substances listed on 205.606.

2. At what point does a substance derived from agriculture stop being agricultural? If so, what could cause it to lose its agricultural status?

The most convenient and practical point at which something STOPS being agricultural is when an agricultural product passes from the world of production to the world of handling. The causative factor would be a non-production event such as processing, including fermenting, extracting, etc. occurs. This may be what the framers of the rule were intending to communicate with their definition of "non-agricultural". Their intention was on target but the broad language of the definition of "agricultural" has put the two definitions in conflict. Use of the ambiguous term "unrecognizable" in the "non-agricultural" definition has drawn attention away from the specific processing activities that the regulation framers foresaw could cause a substance to lose its agricultural status. The inclusion of the phrase "agricultural product" within the "non-agricultural" definition further confused its meaning.

[Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.]

3. Can an agricultural product also be synthetic? If so, can a synthetic agricultural product be certified organic (e.g., soap)?

Yes, agricultural products can be rendered synthetic by virtue of how they are manufactured, according to the current NOP definition of "synthetic." Thus, ascorbic acid, which can be derived from a variety of agricultural sources, is included on Section 205.605(b) as a synthetic nonagricultural substance. Soap, which is listed as a synthetic substance allowed for use in organic crop production on 205.601, can be

certified as organic when identified as an organic oil that has been saponified using a substance (Potassium Hydroxide) that is permitted for use in or on products labeled as "organic." Another example is glycerin, a by-product of saponification that is categorized as synthetic and non-agricultural, even though like soap it is also made from vegetable oil and it is available on the market as a NOP certified organic ingredient

4. If something "is organic" must it be agricultural?

The "organic" definition in the Rule makes great sense. "Organic" is a labeling claim for something produced or handled in accordance with the Rule/OFPA. If we accept that something non-agricultural can bear the "organic" label claim, lots of problems go away.

5. Should there be a list of Prohibited organic products/substances for use in handling?

For example, it might be possible to culture microorganisms on organic substrate, meeting organic processing requirements and produce certified organic preservatives (nisin, natamycin) antibiotics (penicillin) or even poisons (bo-tox, anthrax). There is legal basis for prohibiting "specific natural substances" for handling in the National List at section 2118 of the Act [7 U.S.C. 6517], including paragraphs (a) and (b), and subparagraph (c)(2). This is what 7 USC 6517 says: "the Secretary shall establish a National List of approved and PROHIBITED substances that shall be included in the standards for organic production and HANDLING established under this title . . . " It would be helpful to the organic community to populate the list of what substances should be prohibited in handling products labeled as organic (beyond sulfites, nitrites, and nitrates) and to petition them to the NOSB. This could also reassure consumers about what is not allowed.

Other questions relating to the controversy surrounding allowing yeast and other microorganisms to be designated as agricultural, and thus eligible for organic status including the following:

- 6. Is the possibility of certified organic yeast or bacterial cultures consistent with the principles of organic production and handling?
- 7. Does an "agricultural product" necessarily require a combination of land, soil, and livestock or plant life, or is cultivation (or culture) of a living (non-GMO) organism by humans sufficient to support the possibility that the organism and its derivatives may be organically produced?

There is currently no regulatory benchmark for whether a given substance is "consistent with a system of sustainable agriculture," as stated in the OFPA criterion, although the NOSB developed some detailed factors (April, 2004) to be addressed in evaluating this criterion. Perhaps the most relevant one in the case of non-farm products substances is "Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?" One member of the group offers the following suggestion:

"Even though the 1995 NOSB statement on the "definition of organic" is based on soil-based farming, it can still be a guiding light for this modern discussion with its phrase "ecological production management system." Isn't the point here to have food and fiber produced and processed in an ecologically sound way, managing systems ecologically to sustain and enhance the production of life and the processing of the products of life into other useful forms (goods)? The closer a production system gets to this, the closer it is to coming meeting an ecological production management system standard.

Let's substitute "ecological" for "agricultural" in our thinking so we can focus more on ecological systems management and not go nuts trying to fit aquaculture into agriculture, or ignore the benefits of the ecological production of yeast. If the substance in question is the living product of an ecological production management system, it should be considered agricultural for the purposes of organic production."

- 8. Can a "soilless" operation produce an agricultural product (aka hydroponics, aquaculture)?
- 9. Can an agricultural product be produced in a facility (aka yeast)?

Other potential facility-produced agricultural products might be insect-based fish food, as presented during the November NOSB meeting. Yeast products are also being considered as excellent sources of protein for aquaculture systems, and so could be a valuable organic feed if yeast could be eligible for organic certification. Some presentations at the aquaculture symposium suggested that fully enclosed, facility based aquaculture systems were more ecologically benign, and least likely to disrupt ocean ecosystems, than net pens that permit exchange of nutrients and wastes with the ocean environment.

10. What would be the implications for international equivalency of permitting or not permitting yeast and microbial cultures to be organically produced?

Further analysis concerning the revisions to the EU organic regulations, as well as future updates to the Canadian Permitted Substances List, should be considered in this discussion.